IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/706,104
Inventor(s)	:	Douglas Craig Scott
Filed	:	November 12, 2003
Art Unit	:	1614
Examiner	:	Shirley V. Gembeh
Docket No.	:	9118M
Confirmation No.	:	5134
Customer No.	:	27752
Title	:	Chewable Solid Unit Dosage Forms and Methods For Delivery of Active Agents Into Occlusal Surfaces of Teeth

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

I, Douglas Craig Scott, declare as follows:

1. I am a co-inventor of the subject matter in the application identified above ("the present application").

2. I received a B.S. degree in Pharmacy in 1986 from the University of Cincinnati, College of Pharmacy. I received a Ph.D. in Pharmaceutics in 1991 from the University of Maryland at Baltimore, School of Pharmacy. My expertise is in the areas of pharmaceutical formulation (solids, liquids, semi-solids), drug delivery, controlled release, pharmacokinetics, modeling, and processing. I have multiple publications and patents. Since 1991, I have been employed at the Procter and Gamble Company, where I have worked in multiple health care areas including prescription and over-the-counter drugs (respiratory, gastrointestinal); the last 10 years of my career have been spent in oral care.

3. In May 2007, the oral retention of three samples was evaluated. The three samples were example 8 in US patent 6,706,256 (Lawlor), Eclipse chewing gum, and a BreathSavers mint. Subjects chewed the Lawlor example and BreathSavers mint for about 5 seconds to about 30 seconds and the Eclipse chewing gum for 30 minutes. Any tooth surfaces with visibly retained composition were counted at 5, 10, 20, and 30 minutes. The attached table and accompanying graph, Fig. 1, shows the results of the oral retention evaluation. After 5 minutes, no subject tooth visibly retained any of the three samples. The attached photographs in Fig. 2 are representative images of the subjects' teeth 5 minutes following product use.

4. Also in May 2007, the oral retention of an additional sample, called "Bullseye," was evaluated. Bullseye was a sample of the presently claimed invention, having a retentive agent comprising about 7% hydroxyethyl cellulose and about 4% carboxymethyl cellulose. To evaluate the oral retention of the Bullseye sample, subjects chewed a sample for about 5 seconds to about 30 seconds, brushed their teeth with a manual, flat head, soft toothbrush for about 30 seconds, expectorated the slurry created from the brushing, rinsed with about 10 ml of water, and expectorated again. Visible surfaces with retained composition were counted at 5, 10, 20, and 30 minutes. The attached table and accompanying graph, Fig. 1, shows that the Bullseye sample remained visible on an average of 2.3 tooth sites after 5 minutes, 1.8 sites after 10 minutes, 0.8 sites after 20 minutes, and 0.3 sites after 30 minutes. The attached photographs in Fig. 2 are representative images of the subjects' teeth taken anywhere from 10 to 30 minutes following use of Bullseye, demonstrating the deposition and retention of the Bullseye sample in the subjects' teeth.

Further Declarant sayeth naught.

Douglas Craig Scott

Douglas Craig Scott

Date: 12-9-08

Fig. 1
May-07

Retention Sites Following Product Use

	Lawler Lozenge	Bullseye	Eclipse gum	BreathSavers
5 min	0.0	2.3	0.0	0.0
10 min	0.0	1.8	0.0	0.0
20 min	0.0	0.8	0.0	0.0
30 min	0.0	0.3	0.0	0.0

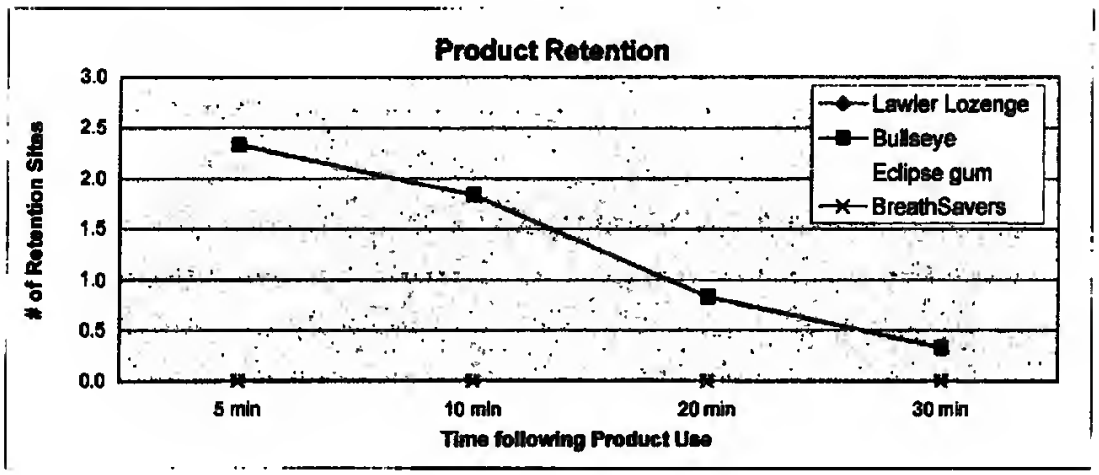
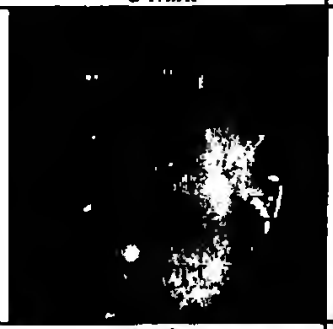
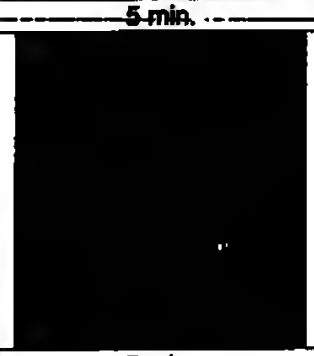
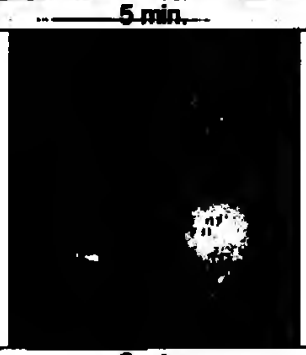


Fig. 2 May 2007

Lawler lozenge formula	Bullseye	Eclipse chewing gum	BreathSavers mint
			Camera Malfunctioned (no image)
5 min.	20 – 30 min.	5 min.	5 min.
			
5 min.	30 + min.	5 min.	5 min.
			
5 min.	20 – 30 min.	5 min.	5 min.
			
5 min.	10 – 20 min.	5 min.	5 min.
			
5 min.	30 min	5 min.	5 min.